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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,416	01/21/2003	Dusan Miljkovic	1000626.0001US1	6979

7590

10/06/2005

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,416

Applicant(s)

MILJKOVIC ET AL

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. In line 1, the recitation of "proximally associated" is not clear as to how the antigen is related to the test surface.

Claim 9 is vague because the recitation of "the microspheres" lacks antecedent support. Claim 9 should probably depend from claim 7.

Claim 12 is vague. The claim recites the use of a chromogenic reaction to detect bound antigen but no reagents are provided for such a chromogenic reaction.

Claim 13 is vague. The claim recites detection of a fluorophor to detect bound antigen but there is no method step for providing the fluorophor.

Claim 14 is vague. In line 1, the recitation of "associated with" is not clear as to how the antigen is related to the solid test environment.

Claim 21 is vague. In line 1, the recitation of "proximally associated" is not clear as to how the antigen is related to the test surface.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5, 6, 10, 11, 12, 13, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Harte.

Harte (US Patent 4,133,639) discloses a body which is suitable for use in the labeled quantitative determination of a biologically derived sample. The body includes a handle attached to at least one non-particulate, nonswellable, impermeable continuous surface region covalently attached to a diagnostic reagent which is reactive with the biologically derived sample. The surface with the attached reagent (i.e. an antibody) is reacted with the sample substance (i.e. an antigen). In one competitive technique, the labeled substance (i.e. fluorochrome labeled antigen) is simultaneously reacted with the sample substance. In a sandwich technique, the labeled substance (i.e. fluorochrome labeled antibody) is subsequently reacted. In any of these techniques, the reaction of the surface and sample is accelerated by stirring with the handle. Then, the surface is conveniently separated from the sample and transported by the handle of the body to a detection station, such as a fluorometer or colorimeter, for measuring the amount of labeled substance without the need to touch the surface (col. 2, line 51, to col. 3, line 34). The body can be in the shape of a cube, cylinder, sphere, etc (col. 8, lines 20-35).

Since the body can be in the shape of a cylinder or sphere, the entire body can rotate via the handle across a test surface and is therefore considered a "roller surface". Since it is not clear as to how the analyte antigen is related to a test surface in the instant claims, the antigen containing liquid samples assayed in Harte using the

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disclosed body is considered to read on the test surface and its proximally associated antigen recited in the claims. Antigen in the liquid sample is proximally associated with the liquid (i.e. test surface) contacting the body. Since Harte teaches stirring the liquid sample with the body, at least part of the body is repeatedly contacting the liquid sample (i.e. test surface) in contact with the body.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin

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Primary Examiner
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10/1/05